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PCB's

Recently, we were informed that in a study by Kimbrough liver carcinomas were observed in female Sherman strain rats fed AROCLOR 1260 for 20½ months. This prompted us to re-examine livers from male and female rats of the Charles River strain which had been fed AROCLOR 1242, AROCLOR 1254, or AROCLOR 1260 for two years in earlier studies conducted for Monsanto Company.

There are four elements which are closely interwoven in this matter: (1) differences in test procedures, (2) differences in results obtained by various investigators, (3) definition of what is a cancer, and (4) evaluation of potential risks, if any, to man. These will be summarized briefly.

1. Several animal studies have been conducted with various brands of PCB's. In some studies, the test material has been identified by trade name (AROCLOR, KANECLOR). In others, there was just a general reference to PCB. Consequently, the quality of test material with respect to the amounts and nature of contaminating impurities or by-products cannot be determined in all cases. In addition, several strains of test animals were used, the duration of the experimental periods varied, and there was a wide range in the depth of detail with which the observations were reported. Consequently, it is difficult to make comparisons between these studies.

2. In general, studies have shown mice to be more susceptible than rats and females to be more sensitive than males to the liver effects of PCB's. Beyond these generalizations, the results have not been consistent. Some investigators have reported liver carcinomas. Others have observed only benign tumors. Several have noted change in liver tissue without detecting tumor formation. For the reasons just cited, it is difficult to determine the bases for these different results. The most direct comparison can be made between the two studies on AROCLOR 1260 since the same high dosage level of the same lot of AROCLOR 1260 was employed in both experiments. In the Kimbrough studies, liver carcinomas were reported to have occurred in approximately 8% of female rats of the Sherman strain (the only sex used). In Monsanto's study, none of the liver lesions had progressed beyond the stage of benign tumors (hepatomas) despite a slightly longer duration of feeding of AROCLOR 1260 to rats of Sprague Dawley, Charles River strain. The Monsanto study employed rats of both sex and it did confirm the previously noted greater sensitivity of female rats to liver effects of PCB's.

3. A review of the liver alterations seen in all three AROCLORS in Monsanto's studies shows that the lesions were benign in character in the traditional pathologic sense. An evaluation of all information available to us, including the contradiction between the recent data showing AROCLOR 1260 to be a carcinogen and our earlier negative results on the same product, leads to a conclusion that AROCLOR 1260 is not carcinogenic to all commonly used strains of laboratory test animals.

4. In 1972, the manufacture of AROCLOR 1260 was discontinued in the United States and the sale of AROCLORS ~~was~~ restricted to a single use, i.e., as dielectric fluids. As such they are used in closed systems which can minimize additional environmental contamination.

There are several factors which must be considered in the continued use of the AROCLORS:

a) There is a high degree of fire risk associated with the use of dielectric fluids and AROCLORS are virtually nonflammable.

b) Though AROCLOR 1260 may have a weak carcinogenic potency, it is no longer used.

c) The dielectric fluids are used in closed systems.

d) Public concern for the AROCLORS is not related to the use of these fluids, but are related to the control of AROCLORS during the changing of condensers and capacitors, and in the recovery of the fluids from used equipment.